



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,513	11/18/2005	Roy R. Lobb	BII-001.01	2848

25181 7590 12/23/2010
FOLEY HOAG, LLP
PATENT GROUP, WORLD TRADE CENTER WEST
155 SEAPORT BLVD
BOSTON, MA 02110

EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT	PAPER NUMBER
----------	--------------

1646

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

12/23/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patent@foleyhoag.com

Office Action Summary	Application No. 10/521,513	Applicant(s) LOBB, ROY R.	
	Examiner JEGATHEESAN SEHARASEYON	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 70-72, 74-77, 79, 80, 85, 99, 105, 106, 108-111, 113, 114, 119, 133 and 139-148 is/are pending in the application.

4a) Of the above claim(s) 105, 106, 108-111, 113, 114, 119 and 133 is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 70-72, 74-77, 79, 80, 85, 99 and 139-148 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/15/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/15/10 has been entered. An action on the RCE follows.

2. Claims 70-72, 74-77, 79, 80, 85, 99, 105, 106, 108-111, 113, 114, 119, 133 and 139-148 are pending. Claims 105, 106, 108-111, 113-114, 119 and 133 remain withdrawn. Therefore claims 70-72, 74-77, 79, 80, 85, 99 and 139-148 are examined.

Information Disclosure Statement

3. The information disclosure filed 7/15/10 has been considered.

4. Any objection or rejection of record, which is not expressly repeated in this action, has been overcome by Applicant's response and withdrawn.

Claim Rejections - 35 USC § 103 (New)

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5a. Claims 70-72, 74-77, 79, 80, 85 and 139-148 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishimo et al. (1998, PTO 1449 of 7/16/10) in view of Pedersen et al. (U. S Patent No. 6, 531, 122) and Chang et al. (U. S Patent No. 5, 908, 626).

Instant invention is drawn to a method of treating glomerulonephritis in mammals by administering interferon- β .

Nishimo et al. (1998) discloses the treatment of membranoproliferative nephritis (glomerulonephritis). The reference also teaches the use of interferon beta (page 406). However, the reference does not teach the use of interferon- β of SEQ ID NO: 4. The reference also does not teach a glycosylated interferon- β or pegylated interferon- β . In addition, the Nishimo et al. reference does not disclose a heterologous polypeptide with immunoglobulin (Ig) molecule.

Pedersen et al. teach various interferon- β preparations. The reference discloses that interferon- β is involved in the immunomodulation of inflammatory disorders (columns 1 and 43). The Pedersen reference teaches mature interferon- β of SEQ ID NO: 2 (columns 1- 3) which is identical to SEQ ID NO: 4 of the instant invention. This

Art Unit: 1646

meets the limitations of the interferon in claims 75 and 76. The glycosylation of interferon- β is disclosed (column 2). This meets the limitation of the interferon in claim 77. Interferon- β -1a and interferon- β -1b are also disclosed (column 2) meeting the limitation of claims 79 and 80. The pegylation of interferon- β is also discussed (column 4 and entire patent).

Chang et al. disclose interferon- β -Fc fusion proteins (columns 1 and 2). This meets the limitations of the interferon in claims 145 and 146.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the instant invention to modify the treatment methods of Nishimo et al.. to treat glomerulonephritis in mammals by administering various interferon- β molecules as disclosed in Pedersen et al and Chang et al. One of ordinary skill in the art would have been motivated to use the methods of Nishimo et al.. to treat glomerulonephritis by administering modified interferon- β because Pedersen et al. and Chang et al. disclose that mature modified interferon- β functions similar to unmodified mature interferon- β .

Further, there is reasonable expectation of success in treating glomerulonephritis because Nishimo et al. discloses that interferon- β has anti-inflammatory properties and glomerulonephritis is an inflammatory disease. The rationale for using modified interferon- β of Pedersen et al. and Chang et al. is to reduce the allergenicity (column 2, Pedersen) and increase the circulating half life of the protein (Chang et al., column 2) . One of ordinary skill in the art would have been motivated use the dosages used in Cruz et al. because they are taught to be clinically effective. Therefore, the instant invention is *prima facie* obvious over Nishimo et al. (1998) in view of Pedersen et al. (U. S Patent

Art Unit: 1646

No. 6, 531, 122) and Chang et al. (U. S Patent No. 5, 908, 626), absent evidence to the contrary.

Conclusion

6. No Claims are allowable.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEGATHEESAN SEHARASEYON whose telephone number is (571)272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol, Ph. D can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

Application/Control Number: 10/521,513

Page 6

Art Unit: 1646

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jegatheesan Seharaseyon,
Examiner, Art Unit 1646

12/18/10